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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,557	03/17/2004	Doug Hui Huang	034827-1402	6217

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FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/803,557

Applicant(s)

HUANG, DOUG HUI

Examiner

Kenneth R. Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 12 is/are allowed.
- 6) ☒ Claim(s) 2,3,5-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY THE
AMENDMENT

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 5-11, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Nguyen et al. ('788) or Stone et al. ('307), in view of either of Morissette et al. or Brezin et al.

Independent amended claim 11 is drawn to methods of detecting a TIGR genotype via single-nucleotide extension assays, wherein the genotype is the polymorphism E423K or N480K.

Nguyen et al. disclose such a method with the exception of detecting the E423K or N480K polymorphism; see columns 2, 3, 6, 26, 27, and 30-33. Specifically, determination of a TIGR genotype or polymorphism is taught in column 2 at lines 54-56; diagnosis or prognosis of glaucoma and selection of treatment regimen is taught in columns 26 and 27; polymerase chain reaction is disclosed at the top of column 31; and single-nucleotide extension assays using labeled ddNTPs are taught in column 30, lines 26-60.

Stone et al. also disclose such a method with the exception of detecting the E423K or N480K polymorphism; see columns 5-6, 43-44, 50-53, 56-57, and 60-61.

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Specifically, determination of a TIGR genotype or polymorphism is taught in columns 5-6; diagnosis or prognosis of glaucoma and selection of treatment regimen is taught in columns 50-51 and 60; polymerase chain reaction is disclosed in column 53, lines 19-22; and single-nucleotide extension assays using labeled ddNTPs are taught in column 56, line 40 to column 57, line 32.

Neither of these primary references discloses detecting the E423K or N480K polymorphism.

Morissette et al. teach the detection and importance of the E423K polymorphism (see entire reference on pages 319-321).

Brezin et al. teach the detection and importance of the N480K polymorphism (see entire reference on pages 438-445).

One of ordinary skill in the art would have been motivated to detect the E423K or N480K polymorphism in the method of either Nguyen et al. or Stone et al. because Morissette et al. and Brezin et al., respectively, taught the detection and importance of these polymorphisms. With respect to the dependent claims further limited as to capillary electrophoresis, fluorescently labeled ddNTPs or sets thereof comprising different and distinguishable labels, or obtaining samples by scraping within the buccal cavity, although these limitations are not explicitly taught in the references, one of ordinary skill in the art would have been motivated to apply them because they were unquestionably conventional in the art and would have provided known and expected benefits: capillary electrophoresis and sets of distinguishably-labeled fluorescent ddNTPs were conventional in nucleic acid separations such as sequencing and

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polymorphism detection; and scraping within the buccal cavity was a conventional, non-invasive means of providing samples for nucleic acid analysis. Thus, such further limitations surely do not contribute towards patentability. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

2. Claims 4 and 12 are allowable. These claims require the use of an oligonucleotide sequence of one of SEQ ID NO:5-8 (claim 4) or 1-4 (claim 12), which oligonucleotide was found to be free of the prior art in the prosecution of the parent '870 application.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

09/12/06